K060901

JUN 29 2006

EXHIBIT C

510(k) SUMMARY OF VASHE™ WOUND CLEANSER

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R §807.92.
Submitter	PuriCore, Inc. 320 King of Prussia Road Radnor, PA 19087
Contact Person	Howard Mann 320 King of Prussia Road Radnor, PA 19087 484-321-2703 610-341-0503 fax
Date Prepared	March 24th, 2006
Trade Name	Vashe™
Common Name	Wound Cleanser
Classification Name	Solution, saline, (wound dressing)
Predicate Device	Allklenz™ Cleanser; Healthpoint Medical K965120, March 21st 1997. CarraKlenz Wound Cleanser; Carrington Laboratories, Inc. K022670, Oct. 17th, 2002. Dermacyn™ Wound Cleanser, Oculus Innovative Sciences, K042729, September 30th, 2004 and Dermacyn™ Wound Dressing, Oculus Innovative Sciences, K041161, February 1st, 2005. Biopure™ MTAD™ Root Canal Cleanser, Dentsply International, K053167, December 8, 2005
Description	The subject device is a wound cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings. The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. Vashe is offered in various volumes.
Indications for Use	Vashe™ Wound Cleanser is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings. The Vashe™ Wound Cleanser is intended for use by qualified health care personnel trained in its use.
Substantial Equivalence	The product is similar in function and intended use to: • Allklenz™ and CarraKlenz Wound Cleansers, manufactured by Healthpoint Medical and Carrington Laboratories, Inc. that include among their labeled uses the cleansing and irrigation of dermal wounds and removal of foreign material. • Dermacyn™ Wound Cleanser and Wound Dressing manufactured by Oculus Innovative Sciences, that include among it's labeled uses the cleansing, moistening and debriding of dermal wounds in addition to moistening and lubricating absorbent wound dressings. • Biopure™ MTAD™ Root Canal Cleanser manufactured by Dentsply International, that include among its labeled uses the cleaning and disinfecting of the root canal system.
Non-clinical Performance	Pre-clinical testing demonstrated biocompatibility of Vashe Wound Cleanser.
Conclusion	Vashe™ Wound Cleanser is substantially equivalent to the currently cleared and marketed Allklenz™ Cleanser, CarraKlenz Wound Cleansers, Dermacyn™ Wound Cleanser, Dermacyn™ Wound Dressing and Biopure™ MTAD™ Root Canal Cleanser

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

PuriCore Inc.
c/o Mr. Howard K. Mann
Vice President Quality Assurance
and Regulatory Affairs
320 King of Prussia Road, Suite 200
Radnor, Pennsylvania 19087

Re: K060901
Trade/Device Name: Vashe™ Wound Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 25, 2006
Received: May 26, 2006

Dear Mr. Mann:

This letter corrects our substantially equivalent letter of June 29, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

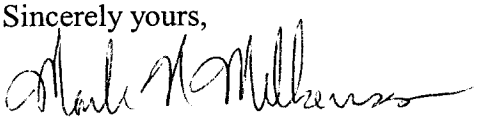
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Exhibit B

Indications for Use

510(k) Number: K060901

Device Name: Vashe™ Wound Cleansing System

Indications For Use:

Vashe™ Wound Cleanser is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

The Vashe™ Wound Cleanser is intended for use by qualified health care personnel trained in its use.

Prescription Use __X____ **(Per 21 CFR 801 Subpart D)** OR **Over-The Counter Use**_____ **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K060901